

DOCKET NO.: WYNC-0331/AM100212(CON)  
PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Megan Tran, et al.

Application No.: 10/661,182

Filing Date: September 12, 2003

For: ANTIDEPRESSANT AZAHETEROCYCLYLMETHYL DERIVATIVES OF  
1,4-DIOXINO[2,3-b]PYRIDINE

Confirmation No.: Not Yet Assigned

Group Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned

DATE OF DEPOSIT: *January 21, 2004*

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*Elizabeth A. McLoud*  
TYPED NAME: Elizabeth A. McLoud

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

- ☒ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of

the above identified application as set forth in § 1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

- ☐ In accordance with § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Certification in Accordance with § 1.97(e) is attached; or

☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

- ☐ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:

☐ Certification in Accordance with § 1.97(e) is attached;

or

☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

- ☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of \$180.00 as set forth in § 1.17(p).

- ☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

- ☒ Copies of references listed on the attached Form PTO-1449 are enclosed herewith
- ☒ Copies of references listed on the attached Form PTO 1449 are not required to be submitted pursuant to the June 30, 2003 recent revisions to 37 CFR § 1.98(a)(2)(i).

**EXCEPT THAT:**

- ☒ In view of the voluminous nature of references **4, 6, 8, 10, 11, 14 and 17**, and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☒ In accordance with § 1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application:
  - ☒ Copies of references **1, 20-25 and 27-32** listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No. **10/127,923**, filed **April 23, 2002**.

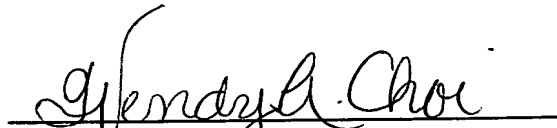
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**PATENT**

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- ☐ The relevance of those listed references which are not in the English language is as follows:
- ☒ There are no listed references which are not in the English language.

Date: *January 21, 2004*

  
Wendy A. Choi  
Registration No. 36,697

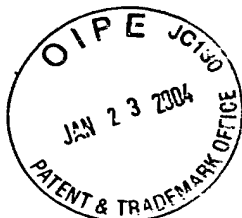
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<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office		Docket No. WYNC-0331/ AM100212(CON)	Application No. 10/661,182
		Applicant Megan Tran, et al.	
		Filing Date September 12, 2003	Group Not Yet Assigned
		Confirmation No. Not Yet Assigned	
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	1	Birch, A.M., "N-substituted (2,3-dihydro-1,4-benzodioxin-2-yl)methylamine derivatives as D <sub>2</sub> antagonists/5-HT <sub>1A</sub> partial agonists with potential as atypical antipsychotic agents," <i>J. Med. Chem.</i> , <b>1999</b> , 42, 3342-3355	
	2	Artigas, F., et al., "Pindolol induces a rapid improvement of depressed patients treated with serotonin reuptake inhibitors," <i>Arch. Gen. Psychiatry</i> , <b>1994</b> , 248-251	
	3	Blier, P., et al., "Effectiveness of pindolol with selected antidepressant drugs in the treatment of major depression," <i>J. of Clinical Psychopharmacology</i> , <b>1995</b> , 15(3), 217-222	
*	4	Bundgaard, (Ed.), <i>Design of Prodrugs</i> , Elsevier, <b>1985</b>	
	5	Bundgaard, H., et al., "(C) Means to enhance penetration; (1) Prodrugs as a means to improve the delivery of peptide drugs," <i>Advanced Drug Delivery Reviews</i> , <b>1992</b> , 8, 1-38	
*	6	Bundgaard, <i>J. of Pharmaceutical Sciences</i> , <b>1988</b> , 7(285 et seq.)	
	7	Bundgaard, H., "Design and Application of Prodrugs," <i>Textbook of Drug Design and Development</i> , Krogsgaard-Larsen, P., et al. (Eds.), <b>1991</b> , Chap. 5, 114-123	
*	8	Eliel, E.L., <i>Stereochemistry of Carbon Compounds</i> , McGraw-Hill, NY, <b>1962</b>	
	9	Hall, M.D., et al., "[ <sup>3</sup> H]8-hydroxy-2-(Di-n-Propylamino)tetralin binding to pre- and postsynaptic 5-hydroxytryptamine sites in various regions of the rat brain," <i>J. Neurochem.</i> , <b>1985</b> , 44(6), 1685-1696	
*	10	Higuchi, et al. (Eds.), <i>Prodrugs as Novel Drug Delivery Systems</i> , American Chemical Society, <b>1975</b>	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	

\* A copy of these references will not be forwarded to the U.S. Patent and Trademark Office since they are believed to be too voluminous and easily obtainable by the Examiner.



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<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
*	11	Jacques, et al., Enantiomers, Racemates and Resolutions, <i>Wiley Interscience</i> , NY, 1981	
	12	Lazareno, S., et al., "Pharmacological characterization of acetylcholine-stimulated [ <sup>35</sup> S]-GYPγS binding mediated by human muscarinic m1-m4 receptors: antagonist studies," <i>Br. J. Pharmacol.</i> , 1993, 109, 1120-1127	
	13	Perez, V., "Randomised, double-blind, placebo-controlled trial of pindolol in combination with fluoxetine antidepressant treatment," <i>The Lancet</i> , 1997, 349, 1594-1597	
*	14	Remington's Pharmaceutical Sciences, 17 <sup>th</sup> Ed., Gennaro, A.R. (Ed.), <i>Mack Publishing Company</i> , Easton, PA, 1985	
	15	Tome, M.B., et al., "Serotonergic autoreceptor blockage in the reduction of antidepressant latency: personality variables and response to paroxetine and pindolol," <i>J. Affect Disord.</i> , 1997, 44, 101-109	
	16	Tome, M.B., et al., "Paroxetine and pindolol: a randomized trial of serotonergic autoreceptor blockade in the reduction of antidepressant latency," <i>Int. Clin. Psychopharmacol.</i> , 1997, 12, 81-89	
*	17	Widder, et al. (Eds.), <i>Methods in Enzymology</i> , Academic Press, 1985, Vol. 4	
	18	Wilen, S.H., et al., "Strategies in optical resolutions," <i>Tetrahedron Report Number</i> 38, <i>Tetrahedron</i> , 1977, 33, 2725-2736	
	19	Wilen, S.H., "Tables of Resolving Agents and Optical Resolutions," <i>Univ. of Notre Dame Press, Notre Dame, IN</i> , E.L. Eliel (Ed.), 1972, page 268-298	
EXAMINER		DATE CONSIDERED	

\* A copy of these references will not be forwarded to the U.S. Patent and Trademark Office since they are believed to be too voluminous and easily obtainable by the Examiner.



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	Applicant Megan Tran, et al.	
	Filing Date September 12, 2003	Group Not Yet Assigned
	Confirmation No. Not Yet Assigned	

**U. S. PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Name	Class	Subclass
	20	5,468,767	11/21/95	Cipollina, et al.		
	21	5,532,241	07/02/96	Bottcher, et al.		
	22	5,741,789	04/21/98	Hibschman, et al.		
	23	5,750,724	05/12/98	Kang, et al.		
	24	5,869,490	02/09/99	Stack		
	25	5,977,106	11/02/99	Patoiseau, et al.		
	26	2002/01843355 A1	12/5/02	Tran, et al.	514	302

**FOREIGN PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Country	Translation	
					YES	NO
	27	WO 95/07274	03/16/95	PCT		
	28	WO 96/24596	08/15/96	PCT		
	29	WO 99/05140	02/04/99	PCT		
	30	WO 01/14330	03/01/01	PCT		
	31	WO 01/49680	07/12/01	PCT		
	32	0 559 285	09/08/93	EPO		

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
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